REMARKS

Claims 1-31 are pending. Claims 17-30 are withdrawn.

Claim Rejections

The Examiner has rejected Claim 1 under 35 USC §102(b) as anticipated by or, in the alternative, under 35 USC §103(a) as obvious over Vallana et al. ("Vallana") (5,084,151). The Examiner states that although Vallana is silent about the presence of the carbon deposit within the stent substance and at a depth within a surface of the stent, the sputtering process as taught by Vallana inherently results in at least some of carbon deposit being present within the substrate substance and at a depth within a surface of the substrate.

Claim 1 recites: "a stent body constructed of material including a stent metallic substance and a **carbon deposit present at a molecular level within the stent metallic substance and at a depth within a surface of the stent.**"

First, Vallana absolutely fails to teach modification of a stent by carbon. Vallana teaches:

> After forming the biocompatible carbon film 4 **on the substrate** 2 in accordance with the present invention, the **coated substrate** 2 is removed from the frame 84 and can be **wrapped around and secured to a stent of a cardiac valve**, for example, to form the prosthetic device 6 shown in FIG. 9. (Col. 7, lines 15-20) (emphasis added).

In other words, **Vallana teaches a carbon film layer on top of a substrate which is later wrapped around a stent**. **Not only is the carbon in Vallana not deposited within the stent, as claimed, but also, the carbon is not even deposited within the substrate used to wrap the stent**. Moreover, the **reference does not teach that the stent is metallic**. Applicants respectfully fail to see how the teachings of this reference are even remotely equivalent to what has been claimed.

Furthermore, contrary to what is contended by the Examiner, Vallana does not even implicitly or inherently teach carbon deposition at a molecular level. To the contrary, **the entire specification of Vallena is directed to carbon coatings and film layers and not carbon deposit at a molecular level** as in Claim 1 of the invention. Val-

lana discloses depositing carbon **films firmly adherent to a substrate** (**i.e., on top of the surface and not within the surface**). Vallana's apparatus is for **coating** carbon on a tubular substrate of a prosthetic device, where sputtered carbon is uniformly **deposited on the exposed surface** of the rotating tubular substrate (Claim 13 and col. 6, lines 30-37). Vallana deposits sputtered carbon atoms on tubular substrate 200 until a uniform thin carbon **film** 201 is obtained (Col. 10, lines 48-53). Vallana **fails to disclose the parameters needed for implanting carbon at a depth within a surface of the stent** as in region 20 below surface 16 depicted in Figure 2B of the present invention.

In sum, nowhere in Vallana are there any teachings or suggestions for **depositing carbon at a depth within a surface of the stent**. Vallana fails to teach deposition into a region of the surface of a stent such that the **sub-surface** properties of a device are modified as in the present invention's Claim 1.

Alternatively, the Examiner asserts that it is well known that the deposit at a depth into a surface of a substrate would have a stronger bond than the deposit just on the surface of the substrate. Therefore, the Examiner asserts that it would have been obvious to one having ordinary skill in the art at the time the invention was made to make sure the sputtering of the carbon would have enough force to implant the carbon into the surface of the substrate in order to create a better bond between the substrate and the deposit.

First, Applicants respectfully submit that the Examiner's contention that one of ordinary skill in the art would want to implant carbon on a sub-surface level since it provides for better adhesive results is tenuous at best. Implanting carbon at a molecular level within the surface of a metallic stent changes the physical properties of the stent. The Examiner has failed to provide an iota of reasoning as to why one or ordinary skill in the art would want to change the physical properties of the stent strut even if better adhesion is at issue.

Moreover, as indicated by the specification, it is not the adhesion of carbon to a metal stent that is at issue, but adhesion of polymers to metals. Metal-to-metal adhesion, such as stainless steel-to-carbon, is typically superior to metal-to-polymer. Yet, Applicants respectfully submit that the Examiner has provided poor reasoning as to why one of ordinary skill in the art would choose carbon deposition at a depth within a surface over

surface deposition on top of a surface. The references that have been cited by the Examiner are directed to surface coating, which in and of itself is evidence that one of ordinary skill in the art prefers coating of carbon over implantation at a molecular level so as to not modify physical properties of the device.

Second, Applicants respectfully traverse the assertion that it is well known that depositing at a depth into a surface of a substrate produces a stronger bond than depositing just onto the surface of the substrate and assert that no evidence has been provided to show that such statements with respect to Claim 1 are well known.

M.P.E.P. §2144.03 states that "the rationale for supporting an obviousness rejection may be based on common knowledge in the art or 'well-known' prior art" and the "Examiner may take official notice of facts outside of the record which are capable of instant and unquestionable demonstration as being 'well-known' in the art." If an applicant traverses such an assertion, the Examiner is required to cite a reference in support of the office's position. If no such reference is provided, Applicants request that the claim rejections that are based on this assertion be removed. Moreover, Applicants request that this statement of facts outside of the record be expressly removed from the record.

Claims 1-16 and 31 are also rejected under 35 USC §103(a) as being unpatentable over Zamora et al. ("Zamora") (6,613,432) in view of Davidson (5,415704). The Examiner asserts that Zamora discloses all the limitations of the claims except a **carbon deposit present at a molecular level within the stent metallic substance and at a depth within a surface of the stent** as recited in Claim 1 of the invention. The Examiner concluded that this deficiency of Zamora is cured by the disclosure of Davidson which suggests "vascular implants having carbon diffused directly into the surface of stainless steel for increasing the surface abrasion resistance and diffusion strengthening to depths of less than 100 microns."

Applicants traverse the rejection based on the following reasons:

1. It is improper to combine references where the references teach away from their combination. In re Grasselli, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). Zamora and Davidson teach away from each other. Zamora is directed **an oxygen or nitrogen plasma deposited surface coating** of sufficient thickness or amount to

impart an anti-restenosis characteristic to **the blood or tissue contacting surface** of the device. In contrast, Davidson teaches "interstitial diffusion" strengthening with oxygen, nitrogen, or carbon. More significantly, Davidson teaches "oxygen, nitrogen, and carbon concentrations **are kept sufficiently low** so that there is **no significant formation of an external** oxide, nitride, or carbide scale so that **an essentially metallic-type appearance remains on the surface** (Col. 9, lines 40-44). Col. 9, lines 61-64 of Davidson further emphasizes the desire to eliminate an external oxide or nitride coating by stating "[i]t should be noted that the internal oxidation and interstitial diffusion hardening methods **can be controlled to minimize or eliminate the formation of an external scale-type coating**."

Simply put, **Davidson teaches against formation of an "external" (i.e., surface coating) oxide or nitride layer while the essence and main objective of the Zamora invention is the formation of an "external" or "surface" oxide or nitride layer of a sufficient thickness to increase the anti-restenosis activity of the blood or tissue contacting surface of the device.** Clearly, this is a classic example of two references teaching away from one another.

2. There is absolutely no motivation to combine Zamora and Davidson. Even though Davidson teaches that the process can be used with cardiovascular devices, Davidson fails to teach the use of stents, specifically. **Stents are not the type of cardiovascular devices that can be subjected to the case hardening treatment of Davidson**. Davidson teaches, for example, increasing the surface hardness of the material **in excess of 60 Rockwell C** (Col. 9, line 46). Stents are deformable structures, subjected to bending, expanding, contracting, cyclic loading or similar stresses. **The application of the case hardening technique of Davidson to the stents of Zamora can lead to cracking of the stents under such stresses**. In the art, hardness of 60 Rockwell C is deemed unsuitable for stent applications.

Moreover, Davidson is directed to devices that need "surface abrasion resistance" improvement (Col. 9, line 25-27). Davidson as a whole teaches devices that are prone to abrasion such as knee joints, hip prosthesis, compression screws and the like. **Stents are**

not in contact with any surfaces that may pose the need of improving the surface abrasion resistance. Rather, one side of the stent contacts a soft vessel wall while the other side contacts bodily fluids. Accordingly, one of ordinary skill in the art would not be motivated to improve the surface abrasion resistance properties of a stent. Thus, there is absolutely no motivation to include the process of Davidson in the stents of Zamora.

Furthermore, with respect to the dependent Claim 8, for example, the tissue-contacting surface of the stent is modified. Considering that the tissue with which a stent has contact is soft tissue, there is absolutely no need to make such surface resistant to abrasion.

Furthermore, with respect to the dependent Claims 3, 4, and 5, for example, the deposition of a polymer layer will make the surface more prone to abrasion and not less. Application of a polymer coating on the modified surface of Davidson would be counter-intuitive to the purpose of the Davidson invention.

3. If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). The combination of Davidson into Zamora renders Zamora unsatisfactory for is intended purpose. Zamora specifically requires modification of its "**tissue or blood contacting surface**" by plasma coating deposition of oxygen or nitrogen. In contrast, Davidson specifically requires diffusion of carbon, oxygen and nitrogen into the surface of the device such that **formation of external scaling is reduced or prevented**. Surface diffusion of carbon, oxygen or nitrogen would render Zamora unsatisfactory for its intended purpose. Zamora requires the oxygen and nitrogen species to be present on its "tissue or bodily fluid contacting surface" in order to decrease adhesion of platelets and leukocytes. If oxygen or nitrogen were diffused into the surface, adhesion of platelets and leukocytes would not be decreased as intended in Zamora. Accordingly, the modification suggested by the Examiner would render Zamora unsatisfactory for its intended purpose.

Applicants respectfully ask that the rejection of independent Claim 1 and its dependent claims be removed. Similarly, Applicants ask that rejection of independent Claim 12 and its dependent claims also be removed for at least the same reasons stated above. Since Claims 1-16 and 31 are in a condition for allowance, please issue a Notice of Allowability. Feel free to contact me if I can be of any assistance.

Respectfully submitted,

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